EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Kimihiro Mabuchi et al.	Art Unit	: 1797
Serial No.	: 10/599,128	Examiner	: Krishnan S. Menon
Filed	: September 20, 2006	Conf. No.	: 4588
Title	: SEPARATION MEMBRANE WITH SELECTIVE PERMEABILITY AND PROCESS FOR PRODUCING THE SAME		

Commissioner for Patents
P.O. Box 1450
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DECLARATION OF MR. KIMIHIRO MABUCHI UNDER 37 C.F.R. § 1.132

I, Kimihiro Mabuchi, hereby declare:

1. I am a co-inventor of the subject matter of the above-captioned application, which relates to separation membranes with selective permeability. At the time the subject invention was made, I served as an institute member in Membrane Research and Development Center of Toyo Boseki Kabushiki Kaisha, Osaka, Japan. I had about nine years' experience in the relevant field at the time the invention was made. I am currently employed by Toyo Boseki Kabushiki Kaisha.

2. I have been advised and understand that claims 1-8, 10, and 12-15 in the above-referenced application are rejected as being obvious over Shimagaki, U.S. Patent No. 6,103,117 ("Shimagaki") in the office action issued on January 5, 2010. Claim 1, the only independent claim, recites a separation membrane having at least the following features:

> (a) a ratio [D]/[C] between the polyvinyl pyrrolidone content [D] in the uppermost layer of a surface on non-blood contacting side and the polyvinyl pyrrolidone content [C] in the uppermost layer of a surface on blood contacting side is 1.1 or higher; and
> (b) when bovine blood at a temperature of 37°C having hematocrit value of 30% and containing 6 to 7 g/dl of total proteins and sodium citrate is flowed through a module containing the separation membrane at a flow rate of 200 ml/min. and a filtration rate of 20 ml/min.:
>
> (i) a sieving coefficient of albumin [A] becomes not less than 0.01 and not more than 0.1 after 15 minutes; and
>
> (ii) a sieving coefficient of albumin [B] becomes not less than 0.005 and less than 0.04 after 2 hours.

3. To compare the membranes described in Shimagaki and the membranes claimed in the present application, I prepared four separation membranes following the procedures described in Examples 4-7 in Shimagaki, which are believed to be the closest examples to the membrane recited in claim 1.

4. Specifically, as shown in Table 1 below, the membranes prepared by Examples 4-7 in Shimagaki have an albumin sieving coefficient between 0.005 and 0.04 after flowing blood through them for 1 hour and might satisfy feature (b)(ii) recited in claim 1 (which requires an albumin sieving coefficient between not less than 0.005 and less than 0.04 after flowing blood through a membrane for 2 hours). On the other hand, the membranes prepared by the Examples in Shimagaki other than Examples 4-7 have an albumin sieving coefficient less than 0.005 after flowing blood through them for 1 hour and, therefore, cannot satisfy feature (b)(ii) recited in claim 1.[1]

Table 1

	Albumin Permeability (%)	Albumin Sieving Coefficient	Notes
Ex. 1	0.12	0.0012	Out of the range in feature (b)(ii)
Ex. 2	0.17	0.0017	Out of the range in feature (b)(ii)
Ex. 3	0.32	0.0032	Out of the range in feature (b)(ii)
CEx. 1	0.12	0.0012	Out of the range in feature (b)(ii)
Ex. 4	**0.75**	**0.0075**	**Might be within the range in feature (b)(ii)**
Ex. 5	**0.58**	**0.0058**	**Might be within the range in feature (b)(ii)**
Ex. 6	**1.38**	**0.0138**	**Might be within the range in feature (b)(ii)**
CEx. 2	0.12	0.0012	Out of the range in feature (b)(ii)
Ex. 7	**1.2**	**0.0120**	**Might be within the range in feature (b)(ii)**
Ex. 8	0.4	0.0040	Out of the range in feature (b)(ii)
Ex. 9	0.1	0.0010	Out of the range in feature (b)(ii)
Ex. 11	0.2 (1.0 m^2)	0.0020	Out of the range in feature (b)(ii)
	0.1 (1.6 m^2)	0.0010	Out of the range in feature (b)(ii)
	0.2 (1.8 m^2)	0.0020	Out of the range in feature (b)(ii)
CEx. 3	0.2	0.0020	Out of the range in feature (b)(ii)
CEx. 4	0.3	0.0030	Out of the range in feature (b)(ii)

[1] A membrane having an albumin sieving coefficient less than 0.005 after flowing blood through the membrane for 1 hour would also have an albumin sieving coefficient less than 0.005 after flowing blood through the membrane for 2 hours

5. The conditions for preparing the membranes in Examples 4-7 described in Shimagaki and the properties of the membranes thus obtained are summarized in Table 2 below. For comparison, Table 2 also includes the conditions for preparing a membrane claimed in the present application and its corresponding properties.

Table 2

		Preferred/Claimed range for Invention	Example 4 (US6103117)	Example 5 (US6103117)	Example 6 (US6103117)	Example 7 (US6103117)	
Film-forming Solution	Polysulfon		18	19	〃	18	
	PVP, parts	M: 10,000 to 1,500,000	K30	〃	K60	K30+K90	
			9	〃	〃	6+3	
	DMAc, parts		71.7	70.7	70.0	71.95	
	Water, parts		1.3	1.3	2.0	1.05	
	PVP/Polysulfon (mass %)	10~18	*50.0*	*47.4*	*47.4*	*50.0*	
	Dissolution condition	Nitrogen atmosphere	*Air atmosphere*	*Air atmosphere*	*Air atmosphere*	*Air atmosphere*	*1
		70deg. or lower, within 3 hours.	*90deg * 12hrs*	〃	〃	*80deg * 12hrs*	
Inner Solution	DMAc/Water	30~60/70~40	*70/30*	〃	*63/37*	60/40	
	Temperature (deg)	0~40	Not controled	〃	〃	〃	
	(Temp. of Film-forming soln.) −(Temp. of Inner soln.)	30~60	Not controled	〃	〃	〃	
Nozzle	Extrusion width of Film-forming Soln.	100μm or lower	50μm (0.3−0.2)mm	〃	〃	〃	
	Temperature (deg)	20~90	〃	〃	〃	30	
Dry Zone	Length (mm)		250	〃	350	250	
	Humidity (%)		85	〃	〃	88	
Coagulation Bath	Composition		〃	〃	〃	DMAc/Water	
	Composition ratio		〃	〃	〃	20/80	
	Temperature (deg)		50	〃	〃	40	
Glycerine Bath	(%)	—	—	—	—	88	
Drying	Temperature (deg)	20~80	65	65	65	65	*2
Spinning Speed	(m/min)		〃	〃	〃	40	
Washing with pure water		Applied	〃	〃	〃	80deg*30min.	
Inner Diameter	(μm)		〃	〃	〃	200	
Outer Diameter	(μm)		〃	〃	〃	280	
Thickness of hollow Fiber	(μm)	25-45	〃	〃	〃	40	
[C]	(mass %)	20-40	35	33	40	*45*	
[D]	(mass %)	25-50	35	31	37	43	
[D]/[C]		1.1 or higher	*1.0*	*0.9*	*0.9*	*1.0*	
[A]		0.01-0.1	0.048	0.035	0.031	0.038	
[B]		0.005-0.04	0.006	*0.003*	0.012	0.013	

Parameters according to the invention

[A]: Sieving coefficient of albumin after 15 minutes
[B]: Sieving coefficient of albumin after 2 hours
[C]: Polyvinyl pyrrolidone content in the uppermost layer of a surface on blood contacting side
[D]: Polyvinyl pyrrolidone content in the uppermost layer of a surface on non-blood contacting side

Note

*1: Condition not clearly described in USP
*2: Condition not clearly described in USP

6. As shown in Table 2, even though the membranes prepared by Examples 4-7 in Shimagaki may have an albumin sieving coefficient that falls within the range in feature (b)(ii) recited in claim 1, they do not possess a [D]/[C] ratio of 1.1 or higher, as recited in feature (a) of claim 1. Specifically, Table 2 shows that the membranes prepared by Examples 4-7 in Shimagaki have a [D]/[C] ratio ranging from 0.9-1.0, which is less than the [D]/[C] ratio of 1.1 or higher recited in feature (a) of claim 1.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: July 1st. 2010

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